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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,291	11/28/2006	Pascale Gaillard	285380US0PCT	6383
1444 7590 04/01/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				
EXAMINER				
BALASUBRAMANIAN, VENKATARAMAN				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
04/01/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/571,291

Applicant(s)

GAILLARD ET AL.

Examiner/Venkataraman
Balasubramanian/**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' response, which included addition of new claims 15-20 and amendment to claims 1-14, filed on 12/19/2008, is made of record. Claims 1-17 are now pending. In view of applicants' amendment to claims 1-14 and addition of new dependent claims 15-20, all 112 second paragraph rejections except that applied to "sulfonyl" made in the previous office action have been obviated. In addition, the following rejections are applied to currently pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of "sulfonyl" in claim 1 renders claim 1 and the dependent claims 2-20 indefinite as a sulfonyl is a divalent group and what else is appended to this group to meet the valence requirement is unclear.

Applicants' argument to overcome this rejection is not persuasive. As recited a sulfonyl is a divalent group. Specification on page 9 recites sulfonyl as monovalent group SO_2R and the definition provided is for monovalent group not divalent group. Thus scope of sulfonyl recited in claims is different from the scope of that is recited in specification. Reading the limitation specification into claims is not proper. Hence, this rejection is proper and is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Halazy et al., WO 01/47920.

Halazy et al., teaches several benzazole compounds useful for treating disorder of immune system cancer, which include instant compounds. See page 9, formula I and note definition of the X, G, L, R¹, and R². Note when X is S, G= pyrimidinyl with L substituents, with given definition of other variable choices, the compounds taught by Halazy et al., include instant compounds. See pages 9-24 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 28-54, for examples of compounds made. See pages 54-55 for pharmaceutical formulation.

This rejection is same as made in the previous office action but now limited claim 12 and 14. Halazy clearly teaches the pharmaceutical composition and method of making such a composition. Note the intended use recited in the instant claims are not given any weight as a pharmaceutical composition of compound is a pharmaceutical composition of compound irrespective of its intended use.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to

give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art."

Instant claim 12 is a pharmaceutical composition of compound claim and is clearly defined by a structure namely a benzothiazole core with a side chain bearing pyrimidine. Omission of the attributes to the compound of genus of claim 1 would not alter the structure of these compounds.

Claims 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaillard et al., WO 03/091249.

Gaillard et al., teaches several benzothiazole compounds useful for treating ischemic disorders, which include instant compounds. See page 3, formula A and note definition of the X, G, R¹, and R². Note when X is S, G= pyrimidinyl with substituents, with given definition of other variable choices, the compounds taught by Gaillard et al., include instant compounds. See pages 3-17 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 20-29, for examples of compounds made. See 29-30 for pharmaceutical formulation.

This rejection is same as made in the previous office action but now limited claim 12 and 14. Halazy clearly teaches the pharmaceutical composition and method of making such a composition. Note the intended use recited in the instant claims are not

given any weight as a pharmaceutical composition of compound is a pharmaceutical composition of compound irrespective of its intended use.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art."

Instant claim 12 is a pharmaceutical composition of compound claim and is clearly defined by a structure namely a benzothiazole core with a side chain bearing pyrimidine. Omission of the attributes to the compound of genus of claim 1 would not alter the structure of these compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halazy et al., WO 01/47920 in view of Bennett et al., Current Opinion in Pharmacology 2003, 3:420-425.

Teachings of Halazy et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Halazy et al., teaches several benzazole compounds useful for treating disorder of immune system cancer, which include instant compounds. See page 9, formula I and note definition of the X, G, L, R¹, and R². Note when X is S, G= pyrimidinyl with L substituents, with given definition of other variable choices, the compounds taught by Halazy et al., include instant compounds. See pages 9-24 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 28-54, for examples of compounds made. Although Halazy et al. teaches several benzothiazole compounds,

Halazy et al., does not exemplify all the compounds of genus of compound of formula I shown in page 9, wherein $X=S$. But Halazy et al., teaches equivalency of alternate choices of all variables including X, with the compounds taught in pages 9-55 with those generically claimed in page 9.

Currently amended claims 1-10,13 and 15-20 related to method of use different from those taught by Halazy et al. However, Halazy et al., teaches such benzothiazoles are useful in inhibiting JNKs and JNKs are known at the time of instant invention to be implicated in metabolic disorder mediated by insulin resistance or hyperglycemia such as diabetes type II, inadequate glucose tolerance and obesity.

For example, Bennett et al., teaches JNK inhibitors to be useful in treating insulin resistance, diabetes and obesity.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made based on to combined the teaching of Halazy and Bennett to make various compounds of formula I as permitted by the reference using teachings of Halazy , and expect resulting compounds to possess the uses taught by the combined art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action but now includes currently pending claims and in view of the applicants' amendment, a secondary reference is applied to support the rejection of method of uses embraced in the amended claims 1-14 and newly added claims 15-20.

For reasons stated above this rejection is proper and s maintained.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaillard et al., WO 03/091249 in view of Bennett et al., Current Opinion in Pharmacology 2003, 3:420-425.

Teachings of Gaillard et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Gaillard et al., teaches several benzothiazole compounds useful for treating ischemic disorders, which include instant compounds. See page 3, formula A and note definition of the X, G, R¹, and R². Note when X is S, G= pyrimidinyl with substituents, with given definition of other variable choices, the compounds taught by Gaillard et al., include instant compounds. See pages 3-17 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 20-29, for examples of compounds made.

Although Gaillard et al. teaches several benzothiazole compounds, Gaillard et al., does not exemplify all the compounds of genus of compound of formula A shown in page 3, wherein X=S. But Gaillard et al., teaches equivalency of alternate choices of all variables with the compounds taught in pages 20-29 with those generically claimed in page 3. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make various compounds of formula A as permitted by the reference using teachings of Gaillard et al., and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Currently amended claims 1-10,13 and 15-20 related to method of use different from those taught by Gaillard et al. However, Gaillard et al., teaches such

benzothiazoles are useful in inhibiting JNKs and JNKs are known at the time of instant invention to be implicated in metabolic disorder mediated by insulin resistance or hyperglycemia such as diabetes type II, inadequate glucose tolerance and obesity.

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Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made based on to combined the teaching of Halazy and Bennett to make various compounds of formula I as permitted by the reference using teachings of Halazy , and expect resulting compounds to possess the uses taught by the combined art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action but now includes currently pending claims and in view of the applicants' amendment, a secondary reference is applied to support the rejection of method of uses embraced in the amended claims 1-14 and newly added claims 15-20. For reasons stated above this rejection is proper and s maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,314,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound and composition embraced in the instant claims are also embraced in the compound and composition claims of the US 7,314,878. Note the intended use recited in the instant claims are not given any weight as a pharmaceutical composition of a compound is a pharmaceutical composition of compound irrespective of its intended use.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that "In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art."

Instant claims are pharmaceutical composition of the benzothiazole compound and is clearly defined by a structure namely a benzothiazole core with a side chain

bearing pyrimidine. Omission of the attributes to the compound of genus of claim 15 would not alter the structure of these compounds.

Thus, one trained in the art would be motivated to make the pharmaceutical composition of compounds of the genus taught therein and arrive at instant compounds and expect these compounds have the use taught therein.

This rejection is same as made in the previous office action but now includes claim 12 and 14 only. Instant claims clearly obvious over the pharmaceutical composition taught in the US7,314,878. Hence, this rejection is proper and is maintained.

Claims 12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 7,259,162. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound and composition embraced in the instant claims are obvious over compounds of claim 15 of the US 7,259,162. Thus, one trained in the art would be motivated to make the compounds of the genus taught therein and arrive at instant compounds and expect these compounds have the use taught therein. Note the intended use recited in the instant claims are not given any weight as a pharmaceutical composition of a compound is a pharmaceutical composition of compound irrespective of its intended use.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes

a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art."

Instant claims are pharmaceutical composition of the benzothiazole compound and is clearly defined by a structure namely a benzothiazole core with a side chain bearing pyrimidine. Omission of the attributes to the compound of genus of claim 12 would not alter the structure of these compounds.

This rejection is same as made in the previous office action but now includes claim 12 and 14 only. Instant claims clearly obvious over the pharmaceutical composition taught in the 7,259,162. Hence, this rejection is proper and is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624

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